

CONFIRMATION COPY
VIA FACSIMILE

AOYAMA & PARTNERS

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August 19, 2004
VIA FACSIMILE

Your Ref.: 38569.00004.JP
Our Ref.: 156895
Japanese Patent Application No. 520010/1996
Applicant: Cosmederm Technologies

Dear Ms. Gardner:

With respect to the above-identified case, this is to advise you that an office action was issued on August 3, 2004.

In the office action, the following references were cited:

- 1: JP-A-02/184617 (corresponding to EP 0 311 260 A2) ✓
- 2: JP-A-05/124941 (corresponding to USP No. 5,348,733)
- 3: JP-A-02/157210 (no patent family; an English abstract attached)
- 4: JP-A-06/080544 (corresponding to EP 0 559 262 A1)
- 5: JP-B-46/010436 (corresponding to GBP No. 1,160,640)
- 6: JP-A-54/059339 (corresponding to USP No. 4,363,794)
- 7: WO94/03147 (JP-A-07/509486)

Respective copies of the office action, References 1-7 and their English counterpart(s) or abstract(s) will follow with a confirmatory copy of this letter.

Anticipating that you are handling the corresponding U.S. application(s) and in view of the Patent Term Guarantee Act of 1999 and the associated rules, i.e., 37 CFR 1.701-1.705, enacted in the United States, we hasten to inform you of the above references.

Briefly, the Examiner raised "novelty" and "obviousness" rejections on the basis of the above References 1-7. In addition, the Examiner raised a few objections to the description in the specification and claims.

Our response to the office action should be filed on or before November 3, 2004 (extendable for three months).

We will provide you with our detailed comments on the office action shortly.

Sincerely yours,
AOYAMA & PARTNERS

(Hiroshi) Kawai
Hiroshi Kawai

HK:nm
Encls.

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Office Action

issued on August 3, 2004

I. The application is to be rejected under Article 29, Paragraph 1 of the Patent Law (novelty) because the inventions of the following claims are disclosed in the following references.

II. The application is to be rejected under Article 29, Paragraph 2 of the Patent Law (obviousness) because the inventions of the following claims would be obvious to those skilled in the art from the following references.

Claims 1-26/References 1-7

References 1-7 disclose compositions for topical application comprising an irritant ingredient such as ethanol, lactic acid or gluconic acid and a divalent tin cation.

- Reference 1: Examples I to XX
- Reference 2: Examples 1 and 7
- Reference 3: Examples 5 and 7
- Reference 4: Tables I and II
- Reference 5: Examples XXI and XXII
- Reference 6: Claims, Examples 2, 6 and 7
- Reference 7: Examples I to IV

III. The application is to be rejected under Article 36 of the Patent Law (insufficient disclosure) because of the following reasons.

- (a) The Examiner recognizes that the present inventions relate to compositions for use in a pharmaceutical application field or a similar field thereto. On the other hand, the specification discloses that the present compositions are effective for inhibition of skin irritation when they are applied to subject's faces, but it fails to disclose pharmacological data which technically support the effects of the compositions when they are used in other application regions than the above region. The specification also fails to provide a sufficiently reasonable explanation (for example, on the basis of action mechanism) demonstrating that the present compositions are effective in other application regions.
Consequently, the specification fails to describe the inventions of claims 1-26 so that those skilled in the art can carry out the inventions.
- (b) The term "irritant ingredient" in claims 1-5, 11-14 and 16-26 is unclear because the range of ingredients encompassed by the term is vague.
- (c) The term "topical" in the claims is unclear because the range of application regions encompassed by the term is vague.

References cited

- 1: JP-A-02/184617 (corresponding to EP 0 311 260 A2)
- 2: JP-A-05/124941 (corresponding to USP No. 5,348,733)
- 3: JP-A-02/157210 (no patent family; an English abstract attached)
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- 6: JP-A-54/059339 (corresponding to USP No. 4,363,794)
- 7: WO94/03147 (JP-A-07/509486)

[Copies of these references and their English counterpart(s) or abstract(s) were attached to our letter of August 19, 2004.]

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European Patent
Office

**SUPPLEMENTARY
EUROPEAN SEARCH REPORT**

Application Number
EP 95 94 4196

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 5 126 135 A (H. YAMADA ET AL.) 30 June 1992 (1992-06-30) * the whole document *	1-22	A61K7/00 A61K7/48
X	FR 2 047 885 A (L. SHERWIN ET AL.) 19 March 1971 (1971-03-19) * the whole document *	1-22	
X	FR 2 361 904 A (D. CULIBRIK) 17 March 1978 (1978-03-17) * the whole document *	1-22	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61K
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search THE HAGUE		Date of completion of the search 4 February 2000	Examiner Glikman, J-F
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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